Maine Department of Health and Human Services

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September 8, 2006

TO: Interested Parties

FROM: J. Michael Hall, Deputy Commissioner for Health
Acting Director, Office of MaineCare Services

SUBJECT: Final Rule: Maine State Services Manual, Chapter 104, Sections 2 and 4, Maine Drugs for the Elderly Benefit (DEL) and Maine Part D Wrap Benefits

This letter gives notice of an adopted rule: Maine State Services Manual, Chapter 104, Sections 2 and 4, Maine Drugs for the Elderly Benefit (DEL) and Maine Part D Wrap Benefits. The Department held a public hearing on July 11, 2006, 442 Civic Center Drive, Augusta, Maine. The comment deadline was July 21, 2006.

The implementation of the Medicare Part D prescription drug benefit has significantly impacted the Low Cost Drugs for the Elderly and Disabled (DEL) benefit. The adopted rules correct and clarify Chapter 104, Sections 2 and 4 of the Maine State Services Manual, previously adopted on April 1, 2006. Changes to Section 2 correct and clarify reimbursement rates for retail and mail order pharmacies, while changes to Section 4 update co-payment information for participants who are dually eligible for the DEL and Part D benefits. Changes to Section 4 also clarify participants' eligibility and coverage for the Part D Wrap Benefit.

Rules and related rulemaking documents may be reviewed and printed from the Office of MaineCare Services website at http://www.state.me.us/bms/rules/gen_other_rules.htm or, for a fee, interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 1-800-423-4331.

If you have any questions regarding the policy, please contact your Provider Relations Specialist at 624-7539, option 8; or 1-800-321-5557, option 8 or TTY: (207) 287-1828 or 1-800-423-4331.

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services, Office of MaineCare Services

CHAPTER NUMBER AND TITLE: Maine State Services Manual, Chapter 104, Sections 2 and 4, Maine Drugs for the Elderly (DEL) Benefit and Maine Part D Wrap Benefit

ADOPTED RULE NUMBER:

CONCISE SUMMARY: The implementation of the Medicare Part D prescription drug benefit has significantly impacted the Low Cost Drugs for the Elderly and Disabled (DEL) benefit. The final rules correct and clarify Chapter 104, Sections 2 and 4 of the Maine State Services Manual, previously adopted on April 1, 2006. Changes to Section 2 correct and clarify reimbursement rates for retail and mail order pharmacies, while Changes to Section 4 update co-payment information for participants who are dually eligible for the DEL and Part D benefits. Changes to Section 4 also clarify participants' eligibility for the Part D wrap benefit.

See http://www.maine.gov/bms/rules/gen_other_rules.htm for rules and related rulemaking documents.

EFFECTIVE DATE: September 15, 2006

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2.01 AUTHORITY

The Maine Drugs for the Elderly Benefit, also referred to as the Maine Low Cost Drugs for the Elderly or Disabled (DEL) Benefit, is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. §254-D. The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the Benefit to the Office of MaineCare Services.

2.02 DEFINITIONS

2.02-1 **Authorized Representative** refers to the Department's authority pursuant to 22 M.R.S.A. § 254-D to enroll and reenroll DEL participants into a Medicare Part D plan, apply for Medicare Part D benefits and subsidies on their behalf, and at the Department's discretion, file exceptions and appeals on behalf of participants. The Department may also identify a designee for this function.

2.02-2 **Beneficiary under Medicare Part D** means a person who is eligible for and enrolled in a Medicare Part D plan.

2.02-3 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

2.02-4 **Coverage Gap (donut hole)** is the portion of the standard Medicare Part D benefit where the Part D plan provides no coverage and the enrollee pays 100% of the prescription after the deductible is met.

2.02-5 **Covered Drug** is a drug for which the Department reimburses under the DEL Benefit. See Subsection 2.05 of this Section.

2.02-6 **DEL Rebate Agreement** is an agreement between the Department and a drug manufacturer that provides that the drug manufacturer will make rebate payments for both the basic and supplemental components of the Benefit.

2.02-7 **Drug Utilization Review (DUR)** means a process designed to ensure that prescriptions are appropriate, medically necessary, cost-effective, and not likely to result in adverse medical results.

2.02-8 **Drug Utilization Review Committee (DUR Committee)** means an advisory committee to the Department of Health and Human Services for the MaineCare Benefit and DEL Benefit, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine. The DUR Committee conducts drug utilization review for the Department.

2.02-9 **Generic Drugs** are drugs other than those defined as brand-name drugs.

2.02 **DEFINITIONS** (cont.)

2.02-10 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.

2.02-11 **MaineCare Benefits Manual (MBM)** is the MaineCare policy set forth in Department of Health and Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.

2.02-12 **MaineCare Member** means a person who receives benefits under the MaineCare Program.

2.02-13 **Maine Maximum Allowable Cost (MMAC)** is the maximum reimbursement amount that is established by the Maine Department of Health and Human Services for certain multiple source drugs.

2.02-14 **Medicare Part D** means the prescription drug benefit program provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.

2.02-15 **Medicare Part D Excluded Drugs** are those drugs not covered by Medicare Part D pursuant to Title XIX, Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8], which the Department will continue to reimburse if otherwise covered under this Section. The Department will post a complete list of these covered drugs on its designated website, and the list will include but not be limited to the following categories of drugs: over the counter drugs, certain weight loss drugs, agents when used for the symptomatic treatment of cough and cold, vitamins/minerals, outpatient drugs for which associated tests or monitoring must be purchased exclusively from manufacturers, barbiturates, and benzodiazepines.

2.02-16 **Medi-Span** is a nationally recognized drug database. The Department uses this database to determine which drugs are defined as brand-name (single-source, cross-licensed or innovator) or generic (multiple-source) drugs for the purposes of calculating reimbursement.

2.02 **DEFINITIONS** (cont.)

2.02-17 **National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R § 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.

2.02-18 **Non-Preferred Drugs** are covered drugs that are not preferred drugs.

2.02-19 **OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.

2.02-20 **Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.

2.02-21 **Participant** is an individual who is eligible for and is receiving the DEL Benefit.

2.02-22 **Pharmacy Provider** is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.

2.02-23 **Preferred Drugs** are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

2.02-24 **Preferred Drug List (PDL)** is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties.

2.02-25 **Retail Pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves DEL participants.

2.02-26 **Telepharmacy** is a method of delivering prescriptions dispensed by a pharmacist to a remote site. Pharmacies using telepharmacy delivery of prescriptions must follow all applicable State and Federal regulations and Maine State Board of Pharmacy rules, including using staff qualified to deliver prescriptions through telepharmacy.

2.02-27 **Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

2.02 **DEFINITIONS** (cont.)

2.02-28 **Usual & Customary Charge** is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.

2.03 **ELIGIBILITY**

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

2.04 **PARTICIPATION IN MEDICARE PART D**

Participants must exhaust other pharmacy benefits including Medicare Part D and MaineCare before using DEL benefits under this Section.

2.04-1 Authorized Representative

The Department may act as an authorized representative for or appoint a designee to act as an authorized representative for participants who are dually eligible for DEL and Medicare Part D.

As an authorized representative, the Department may:

Effective 9/15/06

a. deem eligible and enroll and reenroll participants in a Medicare Part D plan;

b. apply for Medicare Part D benefits and subsidies on behalf of participants;

c. establish rules by which participants may opt out of participation in Medicare Part D; and

d. at its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of participants.

2.04-2 Participants Dually Eligible for Medicare Part D

For participants who are eligible for Medicare Part D, the Department may provide coverage of drugs excluded by Medicare Part D to the same extent that coverage is available to participants who are not eligible for Medicare Part D.

2.05 REQUIREMENTS FOR PHARMACY PARTICIPATION IN DEL

A pharmacy that wishes to submit claims for payment under the Drugs for the Elderly Benefit must:

1. Comply with all provider and administrative process requirements set forth in Chapter 104, Section 1; and

2. Be enrolled as a MaineCare pharmacy provider.

The Department may issue a request for proposals from labelers or manufacturers and issue a contract for the provision of generic drugs. Participating providers may be required by the Department to obtain a generic drug from labelers or manufacturers with which the Department contracts. The Department will notify providers and give instructions for compliance with this provision.

2.06 BENEFITS

Only those drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement are covered in the DEL Benefit. In addition, drugs may be subject to prior authorization and the step order as set forth in this Section. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

2.06-1 Basic Benefit

A. Covered Drugs

1. Prescription Drugs

The Basic benefit covers brand-name and generic drugs when administered for the following conditions and illnesses: heart disease, diabetes, high blood pressure, arthritis, chronic lung disease (including emphysema and asthma), anticoagulation, hyperlipidemia (high cholesterol), incontinence, thyroid disease, osteoporosis (bone density loss), Parkinson's disease, glaucoma, and multiple sclerosis/ amyotrophic lateral sclerosis (Lou Gehrig’s Disease).

2. Over-The-Counter Drugs

Some over-the-counter drugs are covered in the DEL Benefit when the Department determines that they are both cost-effective and that they have a National Drug Code (NDC) number. These drugs will be approved only when the prescriber can demonstrate, with appropriate

2.06 **BENEFITS (cont.)**

medical justification, that the use of these drugs is medically necessary. The Department may exclude from coverage drugs that are equivalent to drugs that are available over-the-counter.

3. Benefits for Medicare Part D Eligible Beneficiaries. The Department will continue to cover Medicare Part D Excluded Drugs for eligible participants so long as those drugs are covered for other DEL participants. The Department will post a complete list of these drugs on its designated website. The Department will also continue DEL coverage for premiums, deductibles, co-payments, and coverage gaps (donut hole) in Medicare Part D coverage, as defined in Chapter 104, Section 4, to the extent that funds are available.

B. Co-Payments

1. For Retail Pharmacies

In the Basic benefit, the participant must pay a co-payment for services requested and rendered from retail pharmacies of 20% of the reimbursement amount as defined in Section 2.11, plus $2 per prescription, not to exceed a 34-day supply for brand-name drugs, and up to and including a 90-day supply for generics.

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2. For Mail Order Pharmacies

In the Basic benefit, the participant must pay a co-payment for services requested and rendered from mail order pharmacies of 20% plus $2 of the reimbursement amount as defined in Section 2.11 for up to a 90-day supply of generic drugs or brand-name drugs.

Effective 9/15/06

2.06-2 **Supplemental Benefit**

A. Covered Drugs

The Supplemental benefit includes all drugs not covered in the Basic benefit, including those used to treat illnesses and conditions not included in the Basic benefit of those manufacturers that have entered a federal rebate agreement and a DEL rebate agreement, as set forth above.

2.06 **BENEFITS (cont.)**

B. Co-Payments

Under the Supplemental benefit, whether obtained through retail or mail order pharmacies, participants must pay 100% of the MaineCare prescription rate for brand-name drugs, as set forth in Subsection 2.11 of this Section, minus $2 per prescription. For generic drugs, participants must pay the sum of $2 plus 20% of the DEL prescription rate as set forth in Section 2.11.

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2.06-3 **Catastrophic Benefit**

A. Covered Drugs

All drugs covered by either the Basic benefit or the Supplemental benefit are covered in the Catastrophic benefit.

B. Eligibility for the Catastrophic Benefit

Participants eligible for Medicare Part D are not eligible for catastrophic benefits under this Section.

Participants who are not Medicare Part D eligible are eligible for the Catastrophic benefit once that participant has paid total co-payments in the DEL benefit of at least $1,000 between August 1 and July 31 of any year(s) in which the participant is eligible, provided that:

1. Only co-payments for those drugs that were included in the DEL Benefit on or before May 31, 2001 apply toward the Catastrophic benefit. A list of those drugs is available from the Department and on the Department's designated website; and

2. Only those co-payments that are tracked through the Department's automated pharmacy management information Point of Purchase System apply toward the Catastrophic benefit.

C. Co-Payments

After the participant has paid a total of $1,000 in co-payments as set forth in 2.06-3(B), the participant may purchase any drugs covered by either the Basic or Supplemental benefit by paying 20% of the reimbursement rate described in Section 2.11 until the next July 31.

2.06 **BENEFITS (cont.)**

2.06-4 **Prior Authorization (PA)**

A. Determining Which Drugs May Be Subject to Prior Authorization

The Department may require prior authorization for certain drugs in the DEL benefit as set forth in this sub-section.

In determining when prior authorization will be required, the Department will consider the recommendations of the DUR Committee. The determination to impose prior authorization will be based on the efficacy, safety, and net cost of any given drug and of the other drugs within the therapeutic category. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at section 2.10 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. The Department may also consider the indications for which the drug may be prescribed, where appropriate.

The Department may require prior authorization of any generic drug that has a net cost that is greater than the net cost of its brand-name version.

The Department, in consultation with the DUR Committee, may determine that the prior authorization requirement may be waived on a case-by-case basis for patients who are established on a drug that otherwise might be subject to prior authorization.

B. Exemptions From Prior Authorization

The Department has the discretion to exempt providers and/or participants from prior authorization requirements. The Department may discontinue these PA compliance exemptions any time with written notice. Exemptions are as described in this Section:

2.06 **BENEFITS (cont.)**

1. Provider Exemptions from Prior Authorization:

   a. Three-Month PA Compliance Exemptions

      Providers may receive a 3-month exemption from prior authorization requirements for certain categories of drugs when they demonstrate high compliance with the Department's PDL. The Department runs quarterly reports to identify providers who prescribe 95% or more of their prescriptions, within certain categories of drugs, in compliance with the PDL. When providers are thus identified, they may receive a 3-month exemption from PA requirements when prescribing drugs for participants within the identified drug categories. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

   b. Twelve-Month PA Compliance Exemptions

      When providers have met all requirements for the 3-month compliance exemption described above, and have received that exemption for 3 out of 4 quarters of a year, the Department may grant a 1-year exemption for prior authorization requirements when prescribing drugs for participants within certain categories of drugs. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

   c. Exemptions for Specialty Providers

      The Department, in consultation with the DUR Committee, and consistent with standards set forth in 2.06-4(A), may waive the prior authorization requirements for specific provider specialists on a drug-by-drug basis.

2. Provider Exemptions from Prior Approval

   a. Primary Insurance Exemptions from Prior Authorization

2.06 **BENEFITS (cont.)**

The Department may waive the prior authorization requirements for participants receiving non-preferred drugs when DEL or MaineCare is the secondary payer.

b. Other Special Exemptions from Prior Authorization for Participants

The Department, in consultation with the DUR Committee, and consistent with standards set forth in 2.06-4(A), may waive the prior authorization requirement for specific drugs or medical conditions, on a drug-by-drug basis for participants who have been established for at least 1 year on a drug that otherwise might be subject to prior authorization.

3. Open-Ended Participant Prior Approval

Participants may receive open-ended PAs for specific drugs after having been established on a non-preferred drug and meeting all other prior authorization requirements for at least 1 year. These open-ended PAs do not need to be renewed on an annual basis. These PAs may be issued after the Department determines that the participant's condition is stable, and will remain unchanged if continued on the specific drug. The Department reserves the right to review the PA status should a new and more efficacious alternative become available.

C. Process for Seeking Prior Authorization

When the Department requires prior authorization, the participant's physician must complete and submit a written form, including any required attachments, documenting the medical necessity of the prescribed drug. The Department may seek information such as documentation of other measures that have been attempted to correct the risk/condition, the timeframe in which those other measures were attempted, and the reason for failure. The prescriber is also required to submit documentation that other drugs in the same therapeutic category are contraindicated.

The Department will notify prescribers of the drugs that are subject to prior authorization and will provide them with forms for requesting authorization setting forth the information needed to approve a request. The list of drugs requiring PA and forms will be available on a website designated by the Department.

2.06 **BENEFITS (cont.)**

The requesting prescriber must complete the form applicable to the drug for which prior authorization is sought. The prescriber must send the completed form to the Department or its designee, as instructed by the Department, by mail, fax or by hand delivery. During regular business days, the Department or its designee will respond to a completed request for prior authorization by fax, telephone or other telecommunications device within 24 hours of receipt.

In an emergency situation, including weekends, holidays, or any other time that the Department or its designee is not able to respond to a completed prior authorization request within 24 hours of receipt, the pharmacist is authorized to provide a one-time 96-hour supply of any prescribed drug that is a covered drug. The Department or its designee shall respond to a completed request under this subpart on the next regular business day. The provision of a 96-hour supply under this subpart does not relieve the prescriber of the obligation to complete and submit the prior authorization request form.

In the event that a prescriber fails to submit a completed form for a drug requiring prior authorization, the Department or its designee may authorize the pharmacy to dispense a one-time 34-day supply of the prescribed drug. The authorization of a 34-day supply under this provision does not relieve the prescriber of the obligation to complete and submit the prior authorization request form. If the prescriber has still failed to submit a completed prior authorization request by the end of the additional 34-day period, the Department will consider any refills of that prescription on a case-by-case basis. The Department may require a provider to redo the prior authorization process every 12 months, or sooner if the participant's medical condition or the prior authorization criteria change.

2.06-5 **Preferred Drug List**

A. General

In order to facilitate appropriate utilization, the Department will establish a list of covered drugs, ordered by therapeutic category. Within each therapeutic category, the Department may designate some or all drugs as preferred on the basis of efficacy, safety, and net cost. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: The American Hospital Formulary Service Drug Information, the United States Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American

2.06 **BENEFITS (cont.)**

Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 2.10 of this rule, as adjusted by any manufacturer rebates and or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose. This listing will be known as the Preferred Drug List or PDL.

In addition to the preferred/non-preferred designation, the PDL may include information such as generic name, strength/unit, National Drug Code identification number, and brand name.

All covered drugs, whether preferred or non-preferred, are available to any eligible participant for whom those drugs are medically necessary. Some drugs must have their medical necessity confirmed for a given participant through the prior authorization process before the Department will provide reimbursement.

B. Step Order

In addition to the preferred/non-preferred designations, the Department may assign some drugs on the PDL a further designation of preference within a therapeutic category. This further designation will be known as step order.

The step order is a means of reducing the need to obtain prior authorization. When a participant has been prescribed all drugs at a higher step(s) within a therapeutic category, the drug at the next lower step will automatically be reimbursed for that participant without requiring prior authorization. Only drugs prescribed to the participant since enrollment and reflected in the Department’s automated pharmacy management information Point of Purchase System will be considered in applying the step order.

C. Notification

The Department will post the PDL on the Department's designated web site. The Department will also provide quarterly notification of the drugs selected for placement on the PDL, and any other changes in the PDL. The list will be provided upon request to participants and providers who do not have Internet access.

2.07 **DISPENSING PRACTICES**

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs.

Mail order pharmacies may only dispense up to 90-day supplies of generic or brand-name drugs. When refilling a prescription through mail order, refills may be provided only at a participant's request; mail order pharmacies may not automatically refill prescriptions for participants.

Providers dispensing prescriptions via telepharmacy must obtain approval from the Department. Providers must assure that participant counseling is available at the remote site from the dispensing provider or the provider delivering the prescription, and that only qualified staff, as defined by the Maine State Board of Pharmacy, deliver prescriptions.

2.08 **FINANCIAL PARTICIPATION (CO-PAYMENT)**

Effective 9/15/06

When the DEL Benefit level requires a co-payment, the Department requires each DEL participant to pay the co-payment for drugs, as set forth above. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

2.09 **ELIGIBILITY CARD**

The Department of Health and Human Services issues an eligibility card to each eligible participant enrolled in the DEL Benefit. A participant must present the eligibility card to the participating pharmacy upon request.

2.10 **AMOUNT AND DURATION OF BENEFITS**

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for DEL have been expended. When necessary, the Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

2.11 **REIMBURSEMENT**

The Department will reimburse participating pharmacies only for drugs that are covered drugs as set forth above.

The DEL Benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

A. The Department may establish the Maine Maximum Allowable Cost (MMAC) for covered drugs, considering the following factors:

2.11 **REIMBURSEMENT (cont.)**

1. Multiple manufacturers;
2. Broad wholesale price span;
3. Availability of drugs to retailers at the selected cost;
4. High volume of utilization; and
5. Bioequivalence or interchangability.

B. For retail pharmacies the amount of reimbursement will be the lowest of the following:

1. For Generic Drugs

a. The usual and customary charge; or

b. The Maine Maximum Allowable Cost plus a $2.35 professional fee; or

c. The Average Wholesale Price minus 14% plus a $2.35 professional fee.

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2. For Brand-Name Drugs

a. The usual and customary charge; or

b. The Average Wholesale Price minus 15% plus a $2.35 professional fee.

C. For mail order pharmacies, the amount of reimbursement will be the lowest of the following:

1. For Generic Drugs

a. The usual and customary charge; or

b. The Average Wholesale Price minus 60% plus $1.00 professional fee except as otherwise noted below, or

c. The Maine Maximum Allowable Cost plus $1.00 professional fee.

2. For Brand-Name Drugs

a. The usual and customary charge; or

b. The Average Wholesale Price minus 20% plus $1.00 professional fee.

2.12 MAINE RETAIL PHARMACY PROVIDER INCENTIVE PAYMENT

The Maine Retail Pharmacy Provider Incentive Payment will recognize pharmacies that provide quality pharmacy care to DEL participants living in rural areas. A retail pharmacy must meet at least one of the following conditions to be eligible for this payment: The retail pharmacy must be: 1) the sole pharmacy provider in a community, as determined by zip code of the pharmacy's location; or 2) an independent pharmacy (an entity or individual with an ownership interest in fewer than 4 pharmacy locations); or 3) a retail pharmacy serving participants in supervised settings outside their immediate area (as determined by zip code) where 50% or more of the participants are outside the pharmacy's immediate area, and at least 100 prescriptions are dispensed per quarter for participants outside its immediate area.

The Department will calculate the incentive payment by creating a percentile score based on criteria described below. Each pharmacy's practices will be compared to other pharmacies and then given an overall ranking. Each eligible pharmacy will be given this performance-based percentage using factors described below. The performance-based percentage will be multiplied by a factor of the amount of prescriptions reimbursed by the pharmacy in the quarter being allocated, such that no pharmacy receives an incentive payment that exceeds 3% of their DEL pharmacy reimbursement in that quarter. The Department will calculate the incentive payment on a quarterly basis and send payments to eligible pharmacies within 30 days following the end of the quarter. The following describes factors considered to calculate the incentive:

1. Access for DEL participants as measured by percentage of unduplicated DEL participants served (50% weight)

2. Pharmacies filling a minimum of 25 compounding prescriptions for DEL participants per month (10% weight)

3. Generic drug utilization rate (5% weight)

4. PDL compliance (10%weight)

5. Ratios of prior authorizations (PA's) submitted to claims paid (5% weight)

6. Ratio of emergency claims paid to claims paid (10% weight)

7. Other third party payer coverage dollars collected (5% weight)

8. Length of time participating in the Maine Rx Plus and Maine Drugs for the Elderly Benefit (5% weight)

2.13 APPEALS

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's benefit. These appeal rights are set forth in Chapter 104, Section 1.

2.14 BILLING INSTRUCTIONS

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.

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SECTION 4 MAINE PART D WRAP BENEFITS ESTABLISHED 1/1/06
LAST UPDATED 9/15/06

4.01 AUTHORITY

This benefit is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. § 254-D. The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the benefit to the Office of MaineCare Services.

4.02 DEFINITIONS

4.02-1 **Authorized Representative** refers to the Department's authority pursuant to 22 M.R.S.A. § 254-D to enroll and reenroll participants into a Medicare Part D plan, apply for Medicare Part D benefits and subsidies on their behalf, and at the Department's discretion, file exceptions and appeals on their behalf. The Department may also identify a designee for this function.

4.02-2 **Beneficiary** under Medicare Part D means a person who is eligible for benefits and enrolled in a Medicare Part D plan.

4.02-3 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

4.02-4 **Covered Drug** is a drug for which the Department reimburses under this benefit. See Subsection 4.05 and Appendix A of this Section.

4.02-5 **Generic Drugs** are drugs other than those defined as brand-name drugs.

4.02-6 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.

4.02-7 **MaineCare Benefits Manual (MBM)** is the MaineCare policy set forth in Department of Health and Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.

4.02-8 **MaineCare Member** means a person who receives benefits under the MaineCare Program.

4.02-9 **Medicare Part D** means the prescription drug benefit program provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.

4.02 **DEFINITIONS (cont.)**

4.02-10 **Medicare Part D Excluded Drugs** are those drugs not covered by Medicare Part D pursuant to Title XIX, Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8], for which the Department will continue to reimburse if otherwise covered under this Section. The Department will post a complete list of these covered drugs on its designated website, and the list will include but not be limited to the following categories of drugs: over the counter drugs, certain weight loss drugs, agents when used for the symptomatic treatment of cough and cold, vitamins/minerals, outpatient drugs for which associated tests or monitoring must be purchased exclusively from manufacturers, barbiturates, and benzodiazepins.

4.02-11 **Medicare Savings Program Eligible** refers to a participant who is also eligible for MaineCare through the Medicare Buy-In Program, as defined in the MaineCare Eligibility Manual (MEM) and designated as QMB, SLMB, or QI.

4.02-12 **National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R § 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.

4.02-13 **Non-Preferred Drugs** are covered drugs that are not preferred drugs.

4.02-14 **OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.

4.02-15 **Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.

4.02-16 **Participant** is an individual who is eligible for and is receiving this benefit.

4.02-17 **Pharmacy Provider** is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.

4.02-18 **Preferred Drugs** are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

4.02-19 **Preferred Drug List (PDL)** is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties. This benefit utilizes the PDL referenced in Chapter 104, Section 2, Drugs for the Elderly.

4.02 **DEFINITIONS (cont.)**

Effective 9/15/06

4.02-20 **Prescription Drug Plan (PDP)** is a Medicare Part D plan provider that is also an approved contractor under contract with the DHHS.

4.02.21 **Retail Pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves DEL participants.

4.02-22 **Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

4.02-23 **Usual & Customary Charge** is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.

Effective 9/15/06

4.02-24 **Wrap Benefits** are benefits offered through this Section that may include assistance with co-payments, deductibles, premiums and gaps in coverage. Wrap benefits vary for some members, and details of the benefit are outlined in the table in Appendix A.

4.03 **ELIGIBILITY**

Effective 9/15/06

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333, and adheres to the additional requirements outlined below. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

DEL participants enrolled in Medicare who are not MaineCare members must be enrolled in an approved PDP that is under contract with the Department in order to be eligible for wrap benefits. The Department will enter enrolled participants into its electronic database. Entry into the Department's electronic database may occur in one of two ways:

Effective 9/15/06

1. Auto-enrollment whereby the Department automatically enrolls the participant into an approved PDP and enters the participant into the Department's database; or

2. Self-enrollment by the participant into an approved PDP. Participants who self enroll must communicate their enrollment to the Department, at which time the Department will confirm the information and enter the participant into its database. Providers should inform participants to call the Department's toll free help line at 1-866-796-2463 to report self-enrollment.

DEL members who are MaineCare members are eligible to receive wrap benefits with any Medicare-approved PDP.

4.04 PARTICIPATION IN MEDICARE PART D WRAP BENEFITS

Participants must exhaust other pharmacy benefits including Medicare Part D and MaineCare before using benefits under this Section.

4.04-1 Authorized Representative

The Department may act as an authorized representative for or appoint a designee to act as an authorized representative for participants who are eligible for Medicare Part D.

As an authorized representative, the Department may:

Effective 9/15/06

a. deem eligible and enroll and reenroll participants in a Medicare Part D plan;

b. apply for Medicare Part D benefits and subsidies on behalf of enrollees;

Effective 9/15/06

c. establish rules by which enrollees may opt out of participation in Medicare Part D; and

d. at its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of enrollees.

4.04-2 Coverage of Drugs Excluded from Coverage Under Medicare Part D

For participants who are eligible for Medicare Part D, the Department may provide coverage of drugs excluded by Medicare Part D to the same extent that coverage is available to participants who are not eligible for Medicare Part D.

4.05 BENEFITS

Effective 9/15/06

As detailed in Chapter 104, Section 2, the DEL benefit is limited to drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement. The Maine Part D Wrap Benefit additionally allows coverage of drugs of manufacturers that may not have both a valid DEL and federal rebate agreement. Drugs may be subject to prior authorization and the step order as set forth in Chapter 104, Section 2. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

4.05-1 Covered Benefits

See the chart in Appendix A for a summary of Covered Benefits under this Section.

4.05-2 Prior Authorization (PA)

The Department may require prior authorization for certain drugs in this benefit, and follows guidelines as set forth in Chapter 104, Section 2.

4.05 **BENEFITS (cont.)**

4.05-3 Preferred Drug List

In order to facilitate appropriate utilization, the Department utilizes the Preferred Drug List as detailed in Chapter 104, Section 2.

4.06 **DISPENSING PRACTICES**

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs.

Drugs must be dispensed according to guidelines detailed in Chapter 104, Section 2.

4.07 **FINANCIAL PARTICIPATION (CO-PAYMENT)**

The Department requires each participant to pay a co-payment for drugs, as set forth in the chart in Appendix A. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

4.08 **ELIGIBILITY LETTER**

The Department of Health and Human Services issues an eligibility card to each eligible participant enrolled in this benefit. A participant must present the eligibility card to the participating pharmacy upon request.

4.09 **AMOUNT AND DURATION OF BENEFITS**

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for this benefit have been expended. The Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

4.10 **REIMBURSEMENT**

The Department will reimburse participating pharmacies only for drugs that are covered drugs as set forth in MaineCare Benefits Manual, Chapter 101, Chapter II, Section 80, Pharmacy Services, or in Maine State Services Manual, Chapter 104, Section 2, Drugs for the Elderly Benefit. This benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

4.11 APPEALS

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant's benefit. These appeal rights are set forth in Chapter 104, Section 1.

4.12 BILLING INSTRUCTIONS

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.

Appendix A- MAINE PART D WRAP BENEFITS
COVERAGE CHART

Eligibility Group	Co-Payment	Premiums	Deductible	Gap	Excluded Drugs*
Dual Eligibles Residing in Nursing Facilities	N/A	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
Dual Eligibles residing in Assisted Living and Level I, II, III and IV PNMI Eligibles (as reimbursed under MaineCare Benefits Manual, Chapter III, Appendices C and F, Section 97, Private Non-Medical Institution Services)	100% of all co-payments	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
All other Dual Eligibles	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and 100% of the cost of generics up to $2.	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
Medicare Savings Program DEL Eligibles (QMB, SLMB, QI)	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and up to $2 per generic.	N/A	N/A	N/A	Covered as paid under Chapter 104, Section 2, DEL Policy
DEL members eligible for Medicare Part D	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and up to $2 per generic.	100% of Part D Premiums	50% of the Part D deductible	Members will have co-pay of 20% plus $2.	Covered as paid under Chapter 104 DEL Policy

* Please see the following website for a list of covered Part D excluded drugs: www.mainecarepdl.org (under “General Pharmacy Info”)